K013614

FEB 01 2002

510(k) Summary

Submitted by: ArmKel LLC
469 North Harrison Street
Princeton, NJ 08543

Contact Person: Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
(609) 655-6308

Date Prepared: November 1, 2001

Proprietary Name: TROJAN® CRYSTAL CLEAR Liquid

Common Name: Personal Lubricant

Classification Name: Patient Lubricant [21 CFR §880.6375]

Predicate Device: H•R® Lubricating Jelly
[Pre-1976 Amendments Device]
TROJAN® *FOR WOMEN* Personal Lubricant
[#K890863]

Description of Device: The TROJAN® CRYSTAL CLEAR Liquid personal lubricant is a water-soluble, greaseless, unscented, clear, colorless liquid, 2.1 oz of which is packaged in a clear plastic bottle.

Intended Use of the Device: A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. The TROJAN® CRYSTAL CLEAR Liquid personal lubricant is principally intended to provide supplemental vaginal lubrication during sexual intercourse, and it may be used with condoms.

Technological Characteristics: There are no exceptional technological characteristics associated with TROJAN® CRYSTAL CLEAR Liquid. Although a proprietary formulation, the basic formulation of TROJAN® CRYSTAL CLEAR Liquid follows that of conventional water–soluble lubricant bases. [*e.g.*, *Remington's* Pharmaceutical Sciences, ed. XIV, 1970, Mack Publishing Co., Easton, PA., Chp 85.] Both the TROJAN® CRYSTAL CLEAR Liquid and the predicate lubricant devices follow conventional formulation concepts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ARMKEL, LLC
% Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
PRINCETON NJ 08543

Re: K013614
Trade/Device Name: TROJAN® Crystal Clear Liquid Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HIS
Dated: November 1, 2001
Received: November 5, 2001

Dear Mr. Kolakowsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K013614

Device Name: TROJAN® CRYSTAL CLEAR Liquid Personal Lubricant

Indications for Use: The TROJAN® CRYSTAL CLEAR Liquid is principally designed to help enhance the sexual experience by providing supplemental vaginal lubrication during sexual intercourse. The TROJAN® CRYSTAL CLEAR Liquid may be used with condoms. The TROJAN® CRYSTAL CLEAR Liquid patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X
(Per 21 CFR §8001.109)

David A. Ogern

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013614